

Pharmacist counseling in a cohort of women with HIV and women at risk for HIV

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Background and methods: Achieving high adherence to antiretroviral therapy for human immunodeficiency virus (HIV) is challenging due to various system-related, medication-related, and patient-related factors. Community pharmacists can help patients resolve many medication-related issues that lead to poor adherence. The purpose of this cross-sectional survey nested within the Women's Interagency HIV Study was to describe characteristics of women who had received pharmacist medication counseling within the previous 6 months. The secondary objective was to determine whether HIV-positive women who received pharmacist counseling had better treatment outcomes, including self-reported adherence, CD4⁺ cell counts, and HIV-1 viral loads.

Results: Of the 783 eligible participants in the Women's Interagency HIV Study who completed the survey, only 30% of participants reported receiving pharmacist counseling within the last 6 months. Factors independently associated with counseling included increased age (odds ratio [OR] 1.28; 95% confidence interval [CI] 1.07–1.55), depression (OR 1.75; 95% CI 1.25–2.45), and use of multiple pharmacies (OR 1.65; 95% CI 1.15–2.37). Patients with higher educational attainment were less likely to report pharmacist counseling (OR 0.68; 95% CI 0.48–0.98), while HIV status did not play a statistically significant role. HIV-positive participants who received pharmacist counseling were more likely to have optimal adherence (OR 1.23; 95% CI 0.70–2.18) and increased CD4⁺ cell counts (+43 cells/mm³, 95% CI 17.7–104.3) compared with those who had not received counseling, though these estimates did not achieve statistical significance.

Conclusion: Pharmacist medication counseling rates are suboptimal in HIV-positive and at-risk women. Pharmacist counseling is an underutilized resource which may contribute to improved adherence and CD4⁺ counts, though prospective studies should be conducted to explore this effect further.

Keywords: human immunodeficiency virus, acquired immunodeficiency syndrome, antiretroviral therapy, community pharmacy, pharmacy practice, women's health

Introduction

Human immunodeficiency virus (HIV) has joined the suite of chronic diseases controlled by long-term medication. Patients who initiate antiretroviral therapy have significantly reduced morbidity and mortality, yet long-term adherence to multicomponent antiretroviral regimens can be challenging, and is typically suboptimal.^{1–3} Barriers to adherence can arise via health systems, such as with complex insurance systems, delayed refills due to multilevel communication, or medication errors. Factors related to antiretroviral therapy, such as pill size and adverse effects, also affect adherence. Lastly, there are a host of patient-level barriers to antiretroviral therapy adherence, including the stigma associated with HIV disease and taking medication, comorbidities such

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as depression or substance abuse, economic hardships that impair obtaining antiretroviral therapy, busy life schedules, lack of understanding about the medications or the importance of adherence, forgetting, and poor motivation.⁴⁻⁶

Patients may seek assistance from their HIV clinicians, but clinicians are often hard pressed for time, or may lack the skill or confidence to address adherence problems.⁷⁻⁹ In an era of expanding medication treatment and decreasing medical provider time, community pharmacists can serve as an important resource for HIV-positive patients and their clinicians. Pharmacists are easily accessible and are trained to help patients solve various medication-related problems that can impair adherence^{10,11} They can provide helpful education on HIV treatment, engage in adherence counseling. They can provide helpful education on HIV treatment, engage in adherence counseling when underutilization is detected, provide medication reminder devices to minimize forgetting, share self-care strategies for mild to moderate side effects, advocate on behalf of a patient experiencing troublesome insurance issues, and link patients to programs to help decrease medication costs.^{10,12,13} By advocating for patients in these and in various other ways, pharmacists can help patients adhere better to their medications.

Pharmacists have the potential to be effective HIV treatment advocates, but it is unclear to what extent HIV-positive patients actually utilize their pharmacists as a resource. The purpose of this study is to look within a cohort of women who are HIV-positive or at risk for HIV infection, to determine the proportion that consult with their community pharmacists, and explore factors associated with receiving pharmacist medication counseling. The secondary objective is to determine whether the subset of HIV-positive women who received pharmacist counseling have better treatment outcomes, including higher self-reported adherence, higher CD4⁺ cell counts, and suppressed HIV-1 viral loads compared with HIV-positive women who do not.

Methods

Study population

We performed a cross-sectional study nested within the Women's Interagency HIV Study (WIHS). The WIHS is the largest prospective, observational cohort study of the natural and treated history of HIV in women in the US. Women in WIHS were enrolled at six sites including Bronx, NY, Brooklyn, NY, Baltimore, MD, Washington DC, Chicago, IL, San Francisco, CA, and Los Angeles, CA, during two recruitment waves in 1994–1995 (n = 2625 women) and 2001–2002 (n = 1143 women). Characteristics of WIHS

participants have been described in previous studies.^{14,15} Participants in WIHS undergo semiannual study visits during which an extensive interview is administered. Inquiries about sociodemographic characteristics, medical care, health status, mental and behavior health issues, and medication use are conducted. Participants have the option of bringing their medications to the study visits to aid identification. A clinical examination and blood drawn for laboratory testing is also performed at each study visit. Study protocols and consent forms have been approved by institutional review boards at each study site.

At visit 27 (October 2007 to April 2008), WIHS participants at five study sites (San Francisco, Chicago, Bronx, Brooklyn, Washington DC, Baltimore) were given a 51-item self-administered questionnaire (ie, in a pharmacy experiences substudy) to assess pharmacy characteristics and utilization, medication-related expenses, participation in adherence programs, and experience with medication errors, missing medications, and privacy violations at the pharmacy. Participants were eligible for the pharmacy experiences substudy if they self-reported taking any prescription medication for more than 10 days out of each month since the last study visit.

Statistical analysis

The primary outcome of interest for this study was a WIHS participant's self-reported receipt of any community pharmacist counseling (yes/no) within the 6 months prior to their study visit (visit 27). Secondary outcomes included antiretroviral therapy adherence (self-reported as either <75%, 75%–94%, 95%–99%, or 100% of antiretroviral therapy doses taken as prescribed, over the last 6 months), and WIHS-measured CD4⁺ cell counts and HIV viral load. CD4⁺ count and viral load were measured in laboratories which participate in National Institutes of Health/National Institute of Allergies and Infectious Diseases quality assurance programs during the same visit the pharmacy experiences substudy questionnaire was completed.

Additional covariates of interest were identified. Race was measured by self-report upon initial WIHS enrollment. Participants' self-reported highest educational attainment, annual household income, employment status, drug and alcohol use in the last 6 months, health insurance, presence of severe depressive symptoms (using the Center for Epidemiologic Studies Depression score \geq 16), and antiretroviral therapy use were measured at visit 27. A participant was categorized as having acquired immunodeficiency syndrome (AIDS) if she had ever self-reported a clinical AIDS diagnosis.

Descriptive statistics were used to characterize the social, demographic, and clinical characteristics of all study participants. To determine which factors were associated with receipt of pharmacist counseling, univariate and multivariate logistic regression models were used to estimate crude and adjusted odds ratios (OR) with 95% confidence intervals (CI). Among the subset of HIV-positive women on antiretroviral therapy, associations between pharmacist counseling and other relevant covariates with the secondary outcomes of self-reported adherence, CD4⁺ cell count, and undetectable viral load were assessed using linear and logistic regression models. Covariates selected for multivariate models were selected based on face validity. STATA version 11.0 (College Station, TX) was used for all analyses and a two-sided *P* value of <0.05 guided interpretation.

Results

Of 2164 WIHS participants, 807 women (37%) self-reported taking prescription medications on a regular basis and completed the pharmacy experiences substudy survey. Twenty-four women were excluded from the analysis because they were missing the primary variable of pharmacist counseling within the last 6 months, leaving 783 eligible participants (36%, Table 1). Overall, only 30% of these eligible participants (*n* = 231) reported pharmacist counseling in the last 6 months. Participants who spoke with a pharmacist were slightly older (46.7 versus 44.1 years, *P* = 0.0002), had severe depressive symptoms (48.1% versus 32.6%, *P* < 0.001), and were more likely to live in certain geographic locations, such as San Francisco. Participants who utilized more than one pharmacy or who reported to have many medication questions were more likely to have spoken to a pharmacist (32.5% versus 20.6% and 7.4% versus 2.0%, respectively both *P* < 0.001). Though patients who had completed high school were less likely to speak to the pharmacist (28.1% versus 35.1%) and patients who reported recreational drug use in the last 6 months were more likely to have spoken to a pharmacist (24.2% versus 18.3%), neither of these associations were statistically significant (*P* = 0.057 and *P* = 0.058, respectively). After adjustment for each variable and for covariates with face validity, increasing age, less education, presence of severe depressive symptoms, and use of more than one pharmacy were independently associated with receipt of pharmacist counseling in the multivariable model. HIV status was not a significant factor affecting whether or not a woman received pharmacist counseling (Table 2).

Among HIV-infected women, having clinical AIDS (49.6% versus 37.9%, *P* = 0.02) and greater number of years

Table 1 Characteristics of WIHS pharmacy care survey respondents^a *N* = 783

Participant characteristics ^b	
HIV positive, <i>n</i> (%)	639 (82)
Age, years, mean (SD)	44.8 (8.96)
Race, <i>n</i> (%)	
Caucasian	149 (19)
African American	522 (67)
Other	112 (14)
Annual household income > \$30,000, <i>n</i> (%)	203 (26)
Has health insurance, <i>n</i> (%)	736 (94)
Finished high school, <i>n</i> (%)	259 (33)
Center for Epidemiologic Studies Depression Scale score ≥ 16	291 (37)
Drug use in the last 6 months, <i>n</i> (%)	157 (20)
Alcohol use over the last 6 months, <i>n</i> (%)	
<3 drinks/week	694 (89)
3–13 drinks/week	68 (9)
>13 drinks/week	21 (3)
WIHS study site, <i>n</i> (%)	
Bronx	93 (12)
Brooklyn	260 (33)
Washington DC	97 (12)
San Francisco Bay Area	195 (25)
Chicago	138 (18)
Uses a chain drugstore as primary pharmacy, <i>n</i> (%)	276 (36)
Picks up their own medicines from the pharmacy, <i>n</i> (%)	684 (87)
Use more than one pharmacy, <i>n</i> (%)	186 (24)
Times per month traveled to pharmacy to pick up medicine (mean, SD)	1 (2.1)
Use a pharmacy more than 20 miles away, <i>n</i> (%)	43 (5)
Often has questions about medicines, <i>n</i> (%)	28 (4)
Spoke with their pharmacist in the past 6 months	231 (30)
HIV-positive survey respondents	
AIDS, <i>n</i> (%)	206 (41)
CD4 ⁺ cell count (cells/mm ³), mean (SD)	551 (308)
HIV viral load (log ₁₀ copies/mL), mean (SD)	2.27 (0.75)
Antiretroviral regimen reported at visit	
NRTI-based regimen	30 (6)
NNRTI-based regimen	161 (32)
PI-based regimen	268 (53)
Other regimen	43 (9)
New antiretroviral therapy reported in last 6 months	6 (1)
Number of years since started antiretroviral therapy	11.4 (3.2)
Self-reported adherence to antiretrovirals over last 6 months	
<75%	19 (4)
75%–94%	72 (14)
95%–100%	410 (82)
Reports participating in an adherence program	30 (6)

Notes: ^aWomen's Interagency HIV Study; ^bPercentages may not add up to 100% due to missing data.

Abbreviations: AIDS, acquired immunodeficiency syndrome; HIV, human immunodeficiency virus; SD, standard deviation; NRTI, nucleoside reverse transcriptase inhibitor; NNRTI, non-nucleoside reverse transcriptase inhibitor; PI, protease inhibitor; WIHS, Women's Interagency HIV Study.

since starting antiretroviral therapy (12.0 versus 11.2 years, *P* = 0.01) were associated with speaking with a pharmacist in the last 6 months. The majority of HIV-positive participants on antiretroviral therapy (81.8%) reported taking their regimen as prescribed 95% of the time or greater. In a multivariable

Table 2 Factors associated with receiving pharmacist medication counseling

Characteristic	Univariate OR (95% CI)	Adjusted OR (95% CI)
HIV-positive	0.87 (0.59–1.28)	0.90 (0.59–1.36)
Age, per 10 years	1.38 (1.16–1.65)*	1.28 (1.07–1.55)*
Race		
Caucasian	Ref	–
African American	0.81 (0.55–1.19)	–
Other	0.89 (0.52–1.51)	–
Annual household income > \$30,000, n (%)	1.00 (0.71–1.43)	–
Has insurance, n (%)	1.59 (0.78–3.25)	1.16 (0.53–2.50)
Finished high school	0.72 (0.52–1.01)	0.68 (0.48–0.98)*
Center for Epidemiologic Studies Depression score > 15	1.91 (1.39–2.62)*	1.75 (1.25–2.45)*
Drug use in the last 6 months	1.43 (0.99–2.07)	1.15 (0.77–1.72)
Alcohol use over the last 6 months		
<3 drinks/week	Ref	–
3–13 drinks/week	1.16 (0.68–1.97)	–
>13 drinks/week	0.97 (0.37–2.53)	–
Uses chain pharmacy as primary pharmacy	0.68 (0.44–1.06)	0.63 (0.39–1.02)
Uses more than one pharmacy	1.86 (1.31–2.63)*	1.65 (1.15–2.37)*
Uses a pharmacy more than 20 miles away	1.45 (0.76–2.74)	–
WIHS study site		
Bronx	Ref	Ref
Brooklyn	1.06 (0.62–1.81)	1.01 (0.58–1.77)
Washington DC	0.71 (0.36–1.38)	0.69 (0.34–1.38)
San Francisco Bay Area	1.81 (1.06–3.11)*	1.51 (0.85–2.70)
Chicago	0.92 (0.51–1.68)	0.84 (0.45–1.59)

Note:*Statistically significant.

Abbreviations: OR, odds ratio; CI, confidence interval; HIV, human immunodeficiency virus; WIHS, Women's Interagency HIV Study.

model, older participants and those who received pharmacist counseling had a higher odds of having optimal self-reported adherence, though the association for pharmacist counseling did not reach statistical significance (OR 1.23, 95% CI 0.70–2.18). As expected, depression, drug or alcohol use, having AIDS, and taking a protease inhibitor-based regimen were negatively associated with optimal adherence (Table 3). In unadjusted analyses, speaking with a pharmacist was associated with a 43 cell/mm³ higher CD4⁺ cell count compared with those who did not talk with the pharmacist (95% CI 17.7–104.3, $P=0.16$). This association accounted for less than 1% of the variability in CD4⁺ cell counts. The point estimate for the association between speaking with a pharmacist and having an undetectable viral load in our sample suggested no effect (OR 0.99, 95% CI 0.64–1.52, $P=0.96$).

Discussion

Our study offers a brief look at community pharmacist counseling in a cohort of women with HIV and women

Table 3 Factors associated with self-reported antiretroviral adherence $\geq 95\%$ amongst HIV-positive participants

	Univariate OR (95% CI)	Adjusted OR (95% CI)
Age (per 10 years)	1.29 (0.99–1.69)	1.54 (1.13–2.10)*
Having health insurance	1.20 (0.39–3.69)	1.01 (0.28–3.66)
Completed high school	0.74 (0.46–1.18)	0.83 (0.50–1.38)
Depression (CESD > 15)	0.42 (0.27–0.67)*	0.50 (0.31–0.83)*
Drug or heavy alcohol (>13 drinks/week) use in last 6 months	0.42 (0.24–0.71)*	0.46 (0.25–0.82)*
Having AIDS	0.46 (0.28–0.73)*	0.45 (0.27–0.75)*
Number of years since started antiretroviral therapy	1.00 (0.93–1.07)	–
Using chain drugstore as primary pharmacy	0.77 (0.43–1.38)	0.77 (0.41–1.45)
Picking up own medicines from pharmacy	0.86 (0.44–1.67)	–
Using more than one pharmacy	0.81 (0.48–1.36)	–
Regimen type		
NNRTI-based	Ref	Ref
PI-based	0.39 (0.22–0.70)*	0.40 (0.22–0.73)*
Other	0.54 (0.25–1.19)	0.51 (0.23–1.16)
Spoke with the pharmacist in the last 6 months	1.13 (0.67–1.90)	1.23 (0.70–2.18)

Note:*Statistically significant.

Abbreviations: AIDS, acquired immunodeficiency syndrome; OR, odds ratio; CI, confidence interval; CESD, Center for Epidemiological Studies Depression Score; NNRTI, nonnucleoside reverse transcriptase inhibitor; PI, protease inhibitor.

with high-risk HIV behaviors. Only a modest proportion of study participants (30%) self-reported receipt of pharmacist counseling in the past 6 months. Recall bias may have underestimated the true proportion of participants who received counseling. Another explanation is that pharmacists may be missing valuable opportunities to detect and intervene on patient adherence and medication problems. The low proportion of participants reporting counseling in our study could be reflective of the WIHS population. Female gender has been associated with underutilization of HIV health care services and this may also be true of HIV pharmacy services.^{16–18} HIV-positive patients may be less likely to seek pharmacist counseling due to concerns about privacy around HIV medications; however, the proportions of HIV-positive and HIV-negative participants reporting pharmacist counseling in our study were similar.¹⁹ Given that pharmacists are a vast potential resource for adherence support, it is important to understand the reasons why participants may not communicate with their pharmacists. These reasons cannot be fully elucidated by our retrospective, survey-based study design and should be further explored in qualitative studies with both patients and pharmacists.

HIV-infected women who did report pharmacist counseling in the past 6 months also reported higher antiretroviral

therapy adherence and increased CD4⁺ cell counts compared with those who had not. These observed associations were small, but positive. Though the point estimates did not achieve statistical significance, our findings are consistent with other studies which found that HIV pharmacists in ambulatory care and inpatient settings had a positive impact on CD4⁺ cell counts and improving antiretroviral adherence, in addition to achieving undetectable HIV viral loads, adjusting for drug interactions, and lowering numbers of office visits.^{20–32,37}

Despite their efforts to improve the health of patients with chronic diseases, the work of community pharmacists in HIV may be underappreciated, and is less frequently described in the literature. Three papers described a pilot program of 10 California community pharmacies that received funding to provide medication therapy management services for HIV-positive patients.^{13,33,34} Services offered in these 10 pharmacies varied greatly; they included adherence enhancements such as refill reminders, reminder packaging, and specialized antiretroviral medication counseling.¹³ At 3 years, HIV-positive patients filling their antiretroviral therapy at the pilot pharmacies ($n = 2234$) demonstrated higher refill adherence (medication possession ratios 69.4% versus 47.3%, $P < 0.001$), and a higher odds of having optimal adherence (OR 2.74, 95% CI 2.44–3.10, after controlling for age, gender, and ethnicity) compared with traditional pharmacies.^{33,34} These pilot programs represent the ideal end of the spectrum of HIV community pharmacy care. Many other community pharmacists might hope to provide this type of high level care for their HIV-positive patients, but may be unable to do so for lack of funding, time, support, or expertise.³⁵

Our study reveals minimal engagement in the potentially beneficial relationship between HIV-positive women and their community pharmacists. This information in itself is valuable, but also speaks to the continued research that needs to be done to understand HIV patient-pharmacist relationships better, the impact of community pharmacy care, and how to optimize elements of HIV pharmacy care to have maximal clinical and adherence impact. It can be challenging to operationalize research on pharmacists' day-to-day practice, yet conducting these types of studies is important to substantiate the benefits of pharmacist counseling on outcomes for HIV and other chronic diseases. With further studies quantifying the health benefits added by the intense participation of community pharmacists on the HIV health care team, funding and support may be made more readily available, and HIV pharmacist services may be made more accessible to all patients.^{24,36}

There are various limitations associated with our study. Our study required participants to self-identify whether or not they had received pharmacist counseling. This could have been subject to recall bias or lack of identification of counseling within an encounter, underestimating the overall penetration of pharmacist counseling. Study participants were already highly adherent to their antiretroviral therapy regimens, leaving minimal room for improvement for any intervention. Participants utilized different pharmacies that may represent very diverse models of HIV pharmacy care. A standardized pharmacist counseling intervention developed in collaboration with local HIV clinics may have a clearer impact on clinical and adherence outcomes for HIV-positive persons. Lastly, confounding by indication could have masked some positive effects of counseling. Patients who appeared to be struggling with adherence (and subsequently having lower CD4⁺ cell counts and increased viral loads) could have been more likely to receive counseling from their pharmacists. If poor adherence prompted pharmacist counseling, this could cause counseling to appear to perform poorly, even if it truly is effective in improving adherence.

Conclusion

Counseling and treatment advocacy by community pharmacists is an underutilized health care resource that has the potential to improve the health of patients with HIV. Our study found a small, positive association between speaking with the pharmacist in the last 6 months and having higher adherence or CD4⁺ cell counts that did not achieve statistical significance. Limitations of our study include possible confounding by indication that could have masked some benefit of counseling and a population of study participants who were already highly adherent to their antiretrovirals. Given the shrinking availability of health care resources today, efforts to develop community pharmacy HIV programs should be coordinated with local clinics to provide the most efficient services, and prospective studies which test the efficacy and impact of these programs should continue to be explored.

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